K122449

JUN 1 3 2013

510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Acacia, Inc.
APPLICANT ADDRESS	785 Challenger Street Brea, CA 92821
APPLICANT PHONE	(714) 257-0470
CONTACT PERSON	Fergie Ferguson
PREPARATION DATE	05/15/13
TRADE NAME:	Enteral Nutrition Warmer
COMMON NAME:	Warmer, Thermal, Infusion Fluid
CLASSIFICATION NAME:	Warmer, Thermal, Infusion Fluid
DEVICE CLASSIFICATION:	Unclassified
PRODUCT CODE	LGZ
PREDICATE DEVICES:	Elltec Enteral Nutrition Warmer (K024373)

Purpose
The purpose of this submission is to introduce a new device for Enteral Nutrition Warming.

Substantially Equivalent To:
The Acacia, Inc. Enteral Nutrition Warmer is substantially equivalent in intended use, principle of operation and technological characteristics to the Elltec Enteral Nutrition Warmer (K024373) for the delivery of enteral fluids.

The Acacia, Inc. Enteral Nutrition Warmer and the Elltec Enteral Nutrition Warmer are both electronically powered dry warmers, which supplies external heat to the outside of the administration set tubing. The flow rates, output temperature, along with dimensions and weight are equivalent.

The table below describes the characteristics reviewed to determine substantial equivalence.

Item Reviewed	Proposed Device	Predicate Device	Equivalence
Intended Use	The Enteral Nutrition Warmer is an electronically powered dry warmer, which supplies external heat to the plastic tubing incorporated administration sets for intermittent use and low	The Enteral Nutrition Warmer LIFORT LT-1 is an electronically powered, dry warmer which supplies external heat to the plastic tubing incorporated administration sets for intermittent use and low	Same

	flow rate applications at 0 to 7mL/min.	flow rate applications at 0 to 7ml/min. The LT-1 is available in two sizes: 4mm and 5mm channels for administration sets.	
Principle of Operation	Electrically powered device that incorporates controlled heat to the outer wall of an extension set that is delivering enteral fluid to the patient.	Electrically powered device that incorporates controlled heat to the outer wall of an extension set that is delivering enteral fluid to the patient.	Same
Materials	All materials are fire rated for the proposed device's intended use	Unknown	All materials are fire rated for the proposed device's intended use
Flow rate	0 to 7mL/min	0 to 7mL/min	Same
Tubing OD size	2.4mm	4.1mm to 5.0mm	Acacia utilizes a more commonly used tubing outer diameter for enteral feeding of premature infants
Number of heaters	One	Unknown	Only one sensor is required for the proposed device to perform as intended
Maximum heating plate temperature	48.8 C	46 C	The proposed device's maximum heating plate temperature does not pose a burn hazard
Output temperature	32 C to 41 C	32 C to 41 C	Same
Temperature sensor	Thermocouple	Thermocouple	Same
Safety feature	Temperature fuse shuts off power in case sensor becomes inoperable	Temperature fuse shuts off power in case sensor becomes inoperable	Same
Electrical source	Standard 120V electrical outlet	Standard 120V electrical outlet	Same
Operating condition	0 C to 40 C	0 C to 40 C	Same
Warmer weight	22.8 ounces	19.75 ounces	The proposed device weighs 3.05 ounces more than the predicate device; however, the unit that warms the tubing

			near bedside only weighs 3 ounces. The predicate device includes the temperature controller and the warming unit all in one unit, which makes the device more difficult to place at the bedside.
Warmer dimensions	4.67in(length) x 3.42in (width) x 0.74in(height)	6.9in(length) x 2.6in(width) x 1.5in(height)	The warming unit footprint of both the proposed and predicate devices is similar. The differences are not significant.

Description of the Device Subject to Premarket Notification:
The Enteral Nutrition Warmer is an electronically powered dry warmer, which supplies external heat to the outside of the administration set tubing. The warmer includes an LED light to indicate the warmer is operating and a switch that will turn the warmer on and off.

The Enteral Nutrition Warmer is reusable and provided non-sterile.

Indications for Use:

The Enteral Nutrition Warmer is an electronically powered dry warmer, which supplies external heat to the plastic tubing incorporated administration sets for intermittent use and low flow rate applications at 0 to 7mL/min.

Technical Characteristics:

The Enteral Nutrition Warmer is the same in indications for use, principle of operation and overall technological characteristic compared to the predicate device.

Performance Data:

A human factors study was conducted to assess the clinical risks related to the use of the Enteral Nutrition Warmer for warming enteral fluids during the feeding of neonatal patients by the hospital NICU staff. All identified risks have been identified and adequately mitigated to ensure the system is safe for use.

The following non-clinical tests were performed to ensure the device is capable of meeting the predicate device's specifications when tested for the addition of enteral fluids to the intended use:

- Maximum temperature outside housing (top)
- Maximum temperature outside housing (bottom)
- Maximum temperature heat sink (tubing track)

510(k) Summary of safety and effectiveness

- Maximum temperature of enteral fluid (portion under heater)
- Maximum temperature of enteral fluid (at extension set feeding tube portion)
- Time to reach nominal temperature

Basis for Determination of Substantial Equivalence:

Since the proposed and predicate devices have no significant technological differences, it is concluded that the proposed device is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 13, 2013

Ms. Fergie Ferguson
Director of Operations
785 Challenger Street
BREA California 92821

Re: K122449
Trade/Device Name: Enteral Nutrition Warner
Regulation Number: Unclassified
Regulation Name: Warmer, Thermal, Infusion Fluid
Regulatory Class: Unclassified
Product Code: LGZ
Dated: May 15, 2013
Received: May 24, 2013

Dear Ms. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS,MA Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122449

Device Name: Enteral Nutrition Warmer

Indications for Use:

The Enteral Nutrition Warmer is an electronically powered dry warmer, which supplies external heat to the plastic tubing incorporated administration sets for intermittent use and low flow rate applications at 0 to 7mL/min.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
2013.06.12 13:47:56
-04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122449